APPENDIX B

to declaration by Tetsuya Gatanaga, Ph.D.

Data from Clinical Trial, Protocol AIT-PAN-20

Meyer Pharmaceuticals LLC BB-IND-6288 Protocol AIT-PAN-201

Survival CYTOIMPLANT

Days Vov-99) The state of the																								
Patient Mayer Sex Baseline Disease Stage Date of Date of Death Initials Date of Date of Death Initials Death of Death Initials Stage IV, T4 N1 MX Z7-Jan-99 Z4-May-99 HGK 73 M Stage IV, T4 N1 MX 31-Mar-99 24-May-99 HGK 75 F Stage IV, T4 N1 MX 31-Mar-99 14-Jul-99 EAR 58 F Stage IV, T4 N1 MX 20-Apr-99 14-Jul-99 EAR 58 F Stage IV, T4 N1 MX 20-Apr-99 14-Jul-99 CEM 58 M Stage IV, T4 N1 MX 25-Feb-99 27-Jul-99 CEM 58 M Stage IV, T4 N1 MX 27-Apr-99 26-Jun-99 NAB 57 M Stage IV, T4 N1 MX 27-Apr-99 26-Jun-99 WLG 57 M Stage IV, T4 N1 MX 07-Sep-99 NIA MAB 57 M² Stage IV, T4 N1 MX 07-Jul-99 01-Aor-99 FMD	Status (as of 10-Nov-99)	Deceased	Deceased	Off Study	Deceased	Off Study	On Study	Deceased	Deceased	Deceased	On Study	Off Study	On Study	Deceased	On Study	Decessed	Off Study	Deceased	On Study	On Study	On Study	On Study	On Study	On Study
Patient Mage Sex Baseline Date of Date of Initials (years) Stage IV, T4 N1 MX 27-Jan-99 MSM 67 F Stage IV, T4 N1 MX 27-Jan-99 HGK 73 M Stage IV, T4 N1 MX 27-Jan-99 LCT 64 F Stage IV, T4 N1 MX 31-Mar-99 LCT 64 F Stage IV, T4 N1 MX 30-Jul-99 DLW 78 M Stage IV, T4 N1 MX 30-Jul-99 A-P 65 F Stage IV, T4 N1 MX 30-Jul-99 CEM 58 M Stage IV, T4 N1 M1 27-Apr-99 REW 54 M Stage IV, T4 N1 M1 14-Jun-99 VFB 85 F Stage IV, T4 N1 M1 14-Jun-99 VFB 85 F Stage IV, T4 N1 M1 17-Jun-99 WLG 57 M Stage IV, T4 N1 MX 07-Jul-99 WLG 57 M Stage IV, T4 N1 MX 07-Jul-99 PAQ 70 M Stage IV, T4 N1 MX 07-Jul-99 <t< td=""><td>Survival Days (as of 10-Nov-99)</td><td>117</td><td>168</td><td>224+</td><td>104</td><td>204+</td><td>103+</td><td>86</td><td>84</td><td>9</td><td>275+</td><td>237+</td><td>190+</td><td>122</td><td>64+</td><td>70</td><td>154+</td><td>25</td><td>114+</td><td>+22</td><td>. +29</td><td>23+</td><td>26+</td><td>29+</td></t<>	Survival Days (as of 10-Nov-99)	117	168	224+	104	204+	103+	86	84	9	275+	237+	190+	122	64+	70	154+	25	114+	+22	. +29	23+	26+	29+
Patient Initials Age Sex Baseline MSM 67 F Stage IV, T4 N1 MX HGK 73 M Stage IV, T4 N1 MX LCT 64 F Stage IV, T4 N1 MX LCT 64 F Stage IV, T4 N1 MX DLW 78 M Stage IV, T4 N1 M1 DLW 78 M Stage IV, T4 N1 M1 REW 54 M Stage IV, T4 N1 M0 NFB 85 F Stage IV, T4 N1 M1 WLG 57 M Stage IV, T4 N1 M1 WLG 57 M Stage IV, T4 N1 MX BFB 65 F Stage II, T3 N1 M0 BFB 65 F Stage II, T3 N1 M0 RMS 7 M Stage II, T3 N1 M0 BFB 65 F Stage II, T3 N1 M0 RES 7 M Stage II, T3 N0 M0 RES 7 M Stage II, T3 N0 M0 RAW 7 M Stage	Date of Death	24-May-99	24-Aug-99	N/A	14-Jul-99	N/A	N/A	22-May-99	21-Jun-99	26-Jun-99	N/A	N/A	N/A	14-Oct-99	N/A	20-May-99	N/A	01-Aug-99	N/A	N/A	N/A	N/A	· N/A	N/A
Patient Initials Age (years) Sex Disease S (years) Baselin Disease S (years) MSM 67 F Stage IV, T4 HGK 73 M Stage IV, T4 LCT 64 F Stage IV, T4 EAR 58 F Stage IV, T4 BA-P 65 F Stage IV, T4 CEM 53 M Stage IV, T4 CEM 53 M Stage IV, T4 VFB 85 F Stage IV, T4 VFB 85 F Stage IV, T4 WLG 57 Mi Stage IV, T4 WLG 57 Mi Stage IV, T4 WLG 57 Mi Stage IV, T4 PAQ 70 M Stage IV, T4 PAQ 70 M Stage IV, T4 RES 70 M Stage IV, T4 RAW 74 M Stage II, T3 RJW 74 M Stage III, T3 F	Date of Randomization	27-Jan-99	09-Mar-99	31-Mar-99	01-Apr-99	20-Apr-99	30-Jul-99	25-Feb-99	29-Mar-99	27-Apr-99	08-Feb-99	18-Mar-99	04-May-99	14-Jun-99	07-Sep-99	11-Mar-99	09-Jun-99	07-Jul-99	19-Jul-99	Ž25-Aug-99	14-Sep-99	18-Oct-99	15-Oct-99	12-Oct-99
Patient Age Initials (years) MSM 67 HGK 73 MAW 67 LCT 64 EAR 58 OLW 78 A-P 65 S-M 33 CEM 58 A-P 65	Baseline Disease Stage		Stage IV, T4 N0 M0	7					7		13						13			Stage II, T3 N0 M0		Stage II, T3 NX MX		
Patient Initials MSM HGK MAWW LCT CEM CEM CEM A-P S-M CEM AMS WLG M-B EMD BFB PAQ RES RJW MJS FJM P-F	Sex	F	Σ	ш	щ	ч	Σ	ш	ц	Σ	Σ	Σ	ш	Σ	Ñ	Н	ш	ш	Σ	Σ	Σ	ш	Σ	ட
	Age (years)	29	73	29	64	58	78	65	33	58	54	53	85	. 79	57.	78	71	65	70	78	74	69	63	63
Site/Patient Number 01-002 01-004 01-005 01-009 01-010 02-053 02-053 02-053 03-104 03-105 03-105 03-106 03-106 03-204 05-204 05-207 05-208 06-251	Patient Initials	MSM	HGK	MAW	LCT	EAR	DLW	A-P	S-M	CEM	REW	DLD	VFB	AMS	WLG	M-B	EMD	BFB	PAQ	RES	RJW	MJS	FJM	P-F
	Site/Patient Number	01-002	01-004	01-005	01-006	01-009	01-010	02-052	02-053	02-054	03-101	03-102	03-104	03-105	03-108	04-151	04-152	05-203	05-204	05-206	05-207	05-208	06-251	08-351

^{*} see footnotes on next page

Meyer Pharmaceuticals LLC
BB-IND-6288
Protocol AIT-PAN-201
Survival
Gemcitabine

Site/Patient Number	Patient Initials	Age (years)	Sex	Baseline Disease Stage	Date of Randomization	Date of Death	Survival Days (as of 10-Nov-99)	Status (as of 10-Nov-99)
01-001	CDR	8.1	Σ	Stage IV, T4 N1 M0	10-Dec-98	03-Nov-99	328	Deceased
01-003	WMH	55	ш	Stage III, T3 N1 M0	15-Feb-99	N/A	268+	Off Study
01-007	REH	53	Σ	Stage IV, T4 N0 MX	06-Apr-99	N/A	218+	On Study
01-008	ADC	59	Ц.	Stage IV, T4 N1 M1	13-Apr-99	17-Aug-99	126	Deceased
02-051	CHS	75	Σ	Stage IV, T4 NX M1	11-Feb-99	N/A	272+	Off Study
02-055	LDR	50	Σ	Stage IV, T4 N1 M0	10-Sep-99	N/A	61+	On Study
03-103	EFK	75	u.	Stage IV, T4 N0 MX	23-Apr-99	N/A	201+	On Study
03-106	R-M	72	Σ	Stage IV, T3 N0 M1	66-Inf-60	N/A	124+	On Study
03-107	CGD	90	щ	Stage II, T3 N0 M0	19-Jul-99	N/A	114+	Off Study
05-201	JLB	79	ட	Stage III, T1 N1 M0	09-Jun-99	N/A	154+	Off Study
05-202	D-S	. 59	Σ	Stage IV, T3 N0 M1	25-Jun-99	N/A	138+	On Study
05-205	EMS	. 72°.	щ	Stage IV, T4 N0 M0	04-Aug-99	N/A	+86	On Study
07-301	RIW	71	L L	Stage IV, T2 N1 M1	18-Oct-99	N/A	23+	On Study

Survival Days = Date of Death (or 10-Nov-99) - Randomization Date

N/A = Not Applicable (death not reported for patient as of 10-Nov-99)

Patients 003 and 107 withdrew from the study upon randomization to Gerncitabine.

Meyer Pharmaceuticals LLC BB-IND-6288 Protocol AIT-PAN-201

Time to Treatment Failure CYTOIMPLANT

_																								
	Reason for Treatment Failure	Progressive Disease	Death	Death	Progressive Disease		Death	Progressive Disease	Death					•										
1	I ime to Treatment Failure (days)	06	85	86	48	92	87	98	84	30	232	66	174	32	N/A	02	62	25	N/A	N/A	N/A	N/A	N/A	N/A
7-7-0	Date of Treatment Failure	27-Apr-99	02-Jun-99	66-InC-70	19-May-99	21-Jul-99	25-Oct-99	22-May-99	21-Jun-99	27-May-99	28-Sep-99	25-Jun-99	25-Oct-99	16-Jul-99	N/A	20-May-99	10-Aug-99	01-Aug-99	N/A	N/A	N/A	N/A	N/A	N/A
	Date of Randomization	27-Jan-99	09-Mar-99	31-Mar-99	01-Apr-99	20-Apr-99	30-Jul-99	25-Feb-99	29-Mar-99	27-Apr-99	08-Feb-99	18-Mar-99	04-May-99	14-Jun-99	07-Sep-99	11-Mar-99	09-Jun-99	07-Jul-99	19-Jul-99	25-Aug-99	14-Sep-99	18-Oct-99	15-Oct-99	12-Oct-99
	Baseline Disease Stage	Stage IV, T4 N1 MX	Stage IV, T4 N0 M0	Stage IV, T4 N0 MX	Stage IV, T4 N1 MX	Stage IV, T4 N1 M1	Stage III, T3 N1 MX	Stage IV, T4 N0 M0	Stage IV, T4 NX M1	Stage IV, T4 N1 M1	Stage III, T3 N1 M0	Stage IV, T4 N1 M0	Stage IV, T4 N0 M0	Stage IV, T4 N1 M1	Stage IV, T4 N0 M1	Stage II, T3 N0 M0	Stage III, T3 N1 M0	Stage IV, T4 N1 MX	Stage IV, T4 N0 M1	Stage II, T3 N0 M0	Stage III, T2 N1 M0	Stage II, T3 NX MX	Stage III, T3 N1 M0	Stage IV, T4 N1 MX
	Sex	Ŧ	Σ	Ľ.	ı	F	M	u	ш	M	Μ	M	Щ	Σ	×.	Ц	· iL	ய	Σ	Μ	M	Ъ	Σ	ı
	Age (years)	29	73	29	64	58	78	65	33	58	54	53	85	79	57	78	71	65	70	78	74	69	. 63	63
	Patient Initials	MSM	HGK	MAW	LCT	EAR	DLW	A-P	S-M	СЕМ	REW	סרם	VFB	AMS	WLG	M-B	EMD	BFB	PAQ	RES	RJW	MJS	FJM	P-F
	Site/Patient Number	01-005	004	01-005	01-006	01-009	01-010	02-052	02-053	02-054	03-101	03-102	03-104	03-105	108	04-151	04-152	05-203	05-204	05-206	05-207	05-208	06-251	08-351

* see footnotes on next page

Meyer Pharmaceuticals LLC BB-IND-6288 Protocol AIT-PAN-201 Time to,Treatment Failure

Gemcitabine

	N/A	N/A	18-Oct-99	Stage IV, T2 N1 M1	F	71	RIW	301
	N/A	N/A	04-Aug-99	Stage IV, T4 N0 M0	П	72	EMS	05-205
	N/A	N/A	25-Jun-99	Stage IV, T3 N0 M1	M	59	D-S	05-202
Patient withdrew consent	50	29-Jul-99	09-Jun-99	Stage III, T1 N1 M0	П	79	JLB	05-201
Patient withdrew consent	0	19-Jul-99	19-Jul-99	Stage II, T3 N0 M0	П	60	CGD	03-107
	N/A	N/A	09-Jul-99	Stage IV, T3 N0 M1	Z	72	R-M	03-106
	N/A	N/A	23-Apr-99	Stage IV, T4 N0 MX	FI	75	EFK	03-103
	N/A	N/A	10-Sep-99	Stage IV, T4 N1 M0	Z	50	LDR	02-055
Progressive Disease	222	21-Sep-99	11-Feb-99	Stage IV, T4 NX M1	Z	75	CHS	02-051
Death	126	17-Aug-99	13-Apr-99	Stage IV, T4 N1 M1	П	59	ADC	01-008
Progressive Disease	66	11-Jun-99	06-Apr-99	Stage IV, T4 N0 MX	Z	53	REH	01-007
Patient withdrew consent	8	23-Feb-99	15-Feb-99	Stage III, T3 N1 M0	FI	55	WMH	003
Progressive Disease	118	07-Apr-99	10-Dec-98	Stage IV, T4 N1 M0	Ν	81	CDR	01-001
Reason for Treatment Failure	Time to Treatment Failure (days)	Date of Treatment Failure	Date of Randomization	Baseline Disease Stage	Sex	Age (years)	Patient Initials	Site/Patient Number

Time to Treatment Failure = Date of Treatment Failure - Date of Randomization

N/A = Not Applicable (no Treatment Failure as of 10-Nov-99)

Patients 003 and 107 withdrew from the study upon randomization to Gemcitabine.

Patient 201 refused to continue therapy.

AE/SAE Listings Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

15DEC1999

Randomized Treatment: Cytoimplant

	3/KOZAREK, RICHARD	2/ERICKSON, RICHARD	1/HAWES, ROBERT	Investigator
104	101 REW	52 54	2	Pat Pat Init
VFB .		CE S P CE		Pat Init
18MAR1999	08FEB1999	25FEB1999 29MAR1999 27APR1999	27JAN1999	Date of
102 DLD	17FEB1999	25FEB1999 08MAR1999 29MAR1999 06APR1999 27APR1999 04MAY1999	27JAN1999 02FEB1999	Date of 1st Treatment
20SEP1999	OBFEB1999 17FEB1999 HOT FLASH LOW BACK OBSTIPATI DARK URIN 18FEB1999 UPPER GIR 20FEB1999 CONSTIPATI 23FEB1999 PANCREATI INFLAMMAT BACK PAIN 04MAR1999 BACK PAIN	1 1 1		Date of Date of 1st Last Treatment Treatment
30MAR 1999 30MAY 1999	17FEB1999 18FEB1999 20FEB1999 23FEB1999	O9MAR1999 CHILLS 15APR1999 FEVER 04MAY1999 FEVER	15APR1999 VOMITING ABDOMINA	Date of Onset
TOZ DLD NAMARIYYY Z4MARIYYY - Z4MARIYYY NAUSEA VOMITING EPIGASTRIC BURNING 30MARIYYY GASTRIC OUTLET OBSTRUCTION 104 VFB .04MAY1999 10MAY1999 20SEP1999 10MAY1999 EPIGASTRIC DISCOMFORT	17FEB1999 HOT FLASH LOW BACK PAIN OBSTIPATION OBSTIPATION DARK URINE 18FEB1999 UPPER GITTH PAIN DECREASED APPETITE 20FEB1999 PANCREATIC 23FEB1999 PANCREATIC INFLAMMATION BACK PAIN 04MAR1999 BACK PAIN	CHILLS FEVER FEVER	- —	Adverse Event
1999-WC0263 06APR1999 1999-WC0263 06APR1999 1999-WC0263 12MAY1999 12MAY1999			1999-WC0346 1999-WC0346	SAE Number
06APR1999 06APR1999 06APR1999 06APR1999 12MAY1999 24MAY1999	17FEB1999 22FEB1999 23FEB1999 22FEB1999 05APR1999 22JUL1999 05APR1999 03MAR1999 03MAR1999	22MAY 1999 29APR 1999 26JJUN 1999	18MAY 1999 18MAY 1999	Date of Resolut.
MA SEC		MICO S	s sev	Severity
Prob Prob Prob Unik	Prob Prob Prob Prob Prob Prob Prob Pros s s Prob Pros s s Pros s Prob Pros s s Prob Pros s s Prob Prob Prob Prob Prob Prob Prob Prob	Poss s	N/A	Relationship to: Injection Stu Procedure Dru
Prob Prob Poss Poss Unik	PPOSS S B B B B B B B B B B B B B B B B B	Poss Prob	Poss	study brug

Date of Last Treatment (Cytoimplant patients) = - ==> Patient not treated with second Cytoimplant as of data cut-off.

Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.

Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown

All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.

More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.

AE/SAE Listings Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

15DEC1999 2

Randomized Treatment: Cytoimplant

8/FAIGEL, DOUGLAS O.	Jacob Lin, Coone	4/GRESS, FRANK	3/KOZAREK, RICHARD	Investigator
351 P-F 120011999 190011999	208 MJS 180CT1999 280CT1999	151 M-B 11MAR1999 22MAR1999 152 EMD 09JUN1999 16JUN1999 204 PAG 19JUN 1999 27JUN 1999	104 VFB 04MAY1999 10MAY1999 20SEP1999 11MAY1999 105 AMS 14JUN1999 23JUN1999 18AUG1999 23JUN1999 108 WLG 07SEP1999 21SEP1999 - 23SEP1999	Pat Date of Da Pat Date of 1st L Pat Init Rand Treatment Tre
- 190CT1999 NAUSEA NAUSEA		- 23MAR1999 INCREASE IN TEMPERATURE - 16JUN1999 GASSINESS NAUSEA VOMITING ABDOMINAL DISCOMFORT	04MAY1999 10MAY1999 20SEP1999 11MAY1999 FEVER, 37.7 C NAUSEA VOMITING CHILLS DIARRHEA ABDOMINAL PAIN 14JUN1999 23JUN1999 NAUSEA/VOMITING 07SEP1999 21SEP1999 - 23SEP1999 FEVER 07SEP1999 21SEP1999 - 23SEP1999 FEVER	Date of Last Date of Treatment Onset Adverse Event
190CT1999 1 290CT1999 1		30MAR1999 17AUG1999 17AUG1999 01AUG1999	12MAY1999 1999-WC0391 12MAY1999 1999-WC0391 12MAY1999 12MAY1999 12MAY1999 12MAY1999 12MAY1999 12MAY1999 12MAY1999 14JUN1999 14JUN1999 14JUN1999 24SEP1999	Date of SAE Number Resolut. Sevi
Mod Poss F	Pross s	Mid Poss Mod Poss Mod Poss Mod Poss Mod Poss Mod Poss	Nod Prob	Relationship to: Injection Stu Severity Procedure Dru
Poss	Poss Poss Prob	B DOLK UNIK	P P P P P P P P P P P P P P P P P P P	study Drug

Date of Last Treatment (Cytoimplant patients) = - ==> Patient not treated with second Cytoimplant as of data cut-off.

Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.

Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown

All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.

More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.

AE/SAE Listings Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

Date: Page:

15DEC1999 3

Randomized Treatment: Cytoimplant

8/FAIGEL, DOUGLAS O. 351 P-F 120CT1999 190CT1999	Investigator	
0. 351 P-I	Pat In	
12001199	t Date of	
9 190011999	1st Treatment	D
	Last	79+6
190011999	Date of Onset	
- 190CT1999 ABDOMINAL TENDERNESS	Pat Date of 1st Last Date of Pat Init Rand Treatment Treatment Onset Adverse Event	
•	SAE Number	
290011999	Date of Resolut.	
M.C	Severity	
Poss	Date of Injection Study Imber Resolut. Severity Procedure Drug	Relationship to:
Poss	Study Drug	ionship to:

Date of Last Treatment (Cytoimplant patients) = - ==> Patient not treated with second Cytoimplant as of data cut-off.

Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.

Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown

All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.

More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.

:` :

AE/SAE Listings Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

Date: 15DEC1999 Page: 4

Randomized Treatment: Gemcitabine

	1/HAWES, ROBERT	Investigator
	1 CDR	Pat Init
	10DEC1998	Date of Rand
	18bEC1998	Date of 1st Treatment
	220011999	Date of Date of 1st Last Treatment Treatment
20JAN1999 PL/ 12MAR1999 LON 16APR1999 LON 23APR1999 LON 23MAY1999 LON 02JUL1999 WBC 30JUL1999 WBC 03SEP1999 WBC 03SEP1999 WBC 03SEP1999 WBC 010CT1999 LON 08OCT1999 LON 15OCT1999 LON LON	31DEC1998	Date of
FFFFFFFFF	10DEC1998 18DEC1998 22OCT1999 31DEC1998 MOUTH SORES	Adverse Event
· · · · · · · · · · · · · · · · · · ·		SAE Number
27JAN1999 19MAR1999 16APR1999 30APR1999 04JUL1999 09JUL1999 09JUL1999 09JUL1999 09JUL1999 09JUL1999 13AUG1999 13AUG1999 13AUG1999 13AUG1999 17SEP1999 17SEP1999 17SEP1999 17SEP1999 17SEP1999 17SEP1999 150CT1999 150CT1999	08JAN1999	Date of Resolut.
70777777	PIN	Severity
**************************************	N/A	Relationship to: Injection Stu
Probable pro	Prob	to: n Study e Drug

Date of Last Treatment (Cytoimplant patients) = - ==> Patient not treated with second Cytoimplant as of data cut-off.

Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.

Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown

All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.

More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.

,..

AE/SAE Listings Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

Date: 15DEC1999 Page: 5

Randomized Treatment: Gemcitabine

Pat Date of Steel of Stee	2/ERICKSON, RÌCHARD		1/HAWES, ROBERT	Investigator
Date of Date of Date of Second Pate of Date of Second Pate of Second Second Pate of Pat	51 CHS	8 ADC	1 CDR 7 REH	Pat Ini
Relations to: To: Date of to: To: Date of to: Date of to: To: Date of to: Resolut. Severity Procedure 220c71999 Mod N/A 220c71999 Mod N/A 20MAY1999 Mod N/A 23JUL1999 Mod N/A 17 20 23JUL1999 Mod N/A LETS 71K 19MAY1999 Mid N/A LETS 60X 19MAY199 Mid N/A LETS 60X 19MAY	11FEB1999 16FE			Date of Rand
Relations to: Date of to: To: Date of to: Resolut. Severity Procedure Date of to: Date of	:B1999 14SEF	R1999 11AUC	C1998 220C1 R1999 16AUC	e of Date st Las
Relations to: Date of to: To: Date of to: Resolut. Severity Procedure Date of to: Date of	04APR15 1999 21SEP15 23FEB15 06APR15 21SEP15 29SEP15	06JUL19 31999 05MAY19 12MAY19 02JUN19	11999 150CT1S 31999 20MAY1S	
## Relations SAE Number Resolut. Severity Procedure	DODG BEACH DOS DEPRESSION DOS DEPRESSION DOS DEPRESSION DOS DEPRESSION DOS DEPRESS OF BREATH DOS DRY MOUTH SHORTNESS OF BREATH DOS DOS DEPRESS HEADACHE HOT FLASHES	HEMATOCRIT 20 POPO DECREASED HEMOGLOBIN (7.7) DECREASED HEMATOCRIT (23) HEMATO	z Q	
Relations to: Injection N/A				SAE Number
Relations to: Injection Procedure N/A N/A N/A N/A N/A N/A N/A N/A N/A N/	16MAR 1999 29SEP 1999 29SEP 1999 29SEP 1999	23JUL 1999 23JUL 1999 19MAY 1999 19MAY 1999 19MAY 1999 24JUN 1999 25JUL 1999 28JUL 1999	220CT 1999 20MAY 1999	Date of Resolut.
		MANAGERIA DE SE	X X X	Severity
Study Drug Prob Prob Prob Prob Prob Prob Prob Prob	*********	******* * * * * * * * * * * * * * * *	2 X X	Relation Tojection Procedure
			Prob	Study Drug

Date of Last Treatment (Cytoimplant patients) = - ==> Patient not treated with second Cytoimplant as of data cut-off.
Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.
Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown
All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.
More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.

. '

AE/SAE Listings Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

150EC1999 6

Randomized Treatment: Gencitabine

								3/1			2/8		
								3/KOZAREK, RICHARD			ERICKSON	Investigator	
		j.	. •					RICHARD			2/ERICKSON, RICHARD	gator	
	106 1							103 EFK			55 LDR	Pat	
÷.	3	:									DR	Pat Init	
	09JUL 1999	,						23APR 1999			10SEP1999	Date of Rand	
· ,i	14JUL 1999							30APR 1999			14SEP1999	1st Treatment	Date of
	106 R-M 09JUL1999 14JUL1999 200CT1999 16JUL1999 04AUG1999 11ANG1988							23APR1999 30APR1999 17SEP1999 03MAY1999			10SEP1999 14SEP1999 210CT1999 29SEP1999 CHILLS	1st Last Treatment Treatment	Date of
24AUG1999 08SEP1999	16JUL 1999 04AUG 1999	18SEP1999 22SEP1999	03SEP1999	02SEP1999	12JUL 1999	27MAY 1999	13MAY 1999	03MAY 1999	120CT 1999	060CT1999	29SEP1999	Date of Onset	
24AUG1999 ANEMIA 08SEP1999 I.V. INFILTRATION			FOLLOWING CHEMOTHERAPY NUMBNESS IN FEET				THROMROCYTOPFNIA	RASH ON CHEST	120CT1999 WEAKNESS EPIGASTRIC PAIN	060CT1999 NAUSEA	CHILLS	Adverse Event	
												SAE Number	
25AUG1999 08SEP1999	01AUG1999 04AUG1999	30SEP1999 30SEP1999		30SEP1999	26JUL 1999 26JIII 1999	03JUN1999	20MAY1999	06MAY 1999		29SEP1999	29SEP1999	Date of Resolut.	
<u> </u>				M M C			<u> </u>		<u> </u>	<u> </u>	od.	Severity	
N N N		× × ×	N/A	X X X	E N	× × ×	E / A	N/A	N/N/A	N	N/A	Injection Procedure	Relationship to:
Prob	, , , , , , , , , ,	ק ק ק ק ק ק ק ק	Pro	Prob	777	9 P P	P 70	Pro	Poss	Poss	Poss	Bu'ng Aprits	i.

Date of Last Treatment (Cytoimplant patients) = - ==> Patient not treated with second Cytoimplant as of data cut-off.

Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.

Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown

All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.

More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.

.. ...

AE/SAE Listings Adverse Events Possibly/Probably Related to Injection Procedure and/or Study Drug

15DEC1999 7

Randomized Treatment: Gemcitabine

	5/NGUYEN, CUONG	3/KOZAREK, RICHARD	Investigator	
205 EMS	201 JLB	106 R-M	Pat Init	
04AUG1999	09JUN1999	09JUL 1999	Pat Date of Pat Init Rand	
15JUL 1999 AREMIA 15JUL 1999 GAREMIA INFECT GRAM N 205 EMS 04AUG1999 13AUG1999 18OCT1999 03SEP1999 ANEMIA	21JUN1999	14 JUL 1999	1st Treatment	Date of
180CT1999	13JUL 1999	200CT 1999	Last Treatment	Date of Date of
15JUL 1999 03SEP1999	06JUL 1999	200CT 1999	Date of Onset	
15JUL1999 GALEBLADER FLUID 15JUL1999 GALEBLADER FLUID INFECTION +CULTURE GRAM NEG RODS 205 EMS 04AUG1999 13AUG1999 18OCT1999 03SEP1999 ANEMIA	THROMBOCYTOPENIA	106 R-M 09JUL1999 14JUL1999 200CT1999 200CT1999 NEUTROPENIA	of 1st Last Date of Treatment Treatment Onset Adverse Event	
			SAE Number	
UUAUG1999	13JUL 1999	03NOV1999	Date of Injection	
8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8	M	Z.	Severity	
N N/A	N/A	N/A	Injection Procedure	Relationsh to:
Poss Prob	Prob	Prob	Study	onship

Date of Last Treatment (Cytoimplant patients) = - ==> Patient not treated with second Cytoimplant as of data cut-off.

Date of Resolution = - ==> if date is not given, event is ongoing or date of resolution is unavailable.

Special Missing values: N = Not Applicable; D = Not Done; A = Not Available; U = Unknown

All Adverse Events associated with an SAE number have been reported as a Serious Adverse Event only if YES is noted in the Serious column.

More than one adverse event may have been reported with an SAE. These events are the signs and symptoms of the diagnosis.

ē,